Review of "Exposure Analysis for Dioxins, Dibenzofurans, and CoPlanar Polychlorinated Biphenyls in Sewage Sludge, Technical Background Document"

By
Dr. Curtis Travis

Background

This document describes the risk assessment conducted to determine the total concentrations of polychlorinated-p-dioxins, dibenzofurans, and coplanar polychlorinated biphenyls that can be present in biosolids and remain protective of human health. The risk-based concentration limit is designed to be protective of farmers and their children who apply biosolids to their croplands and pastures and consume home-produced foods.

EPA used both a probabilistic analysis and a deterministic analysis. The probability analysis produces a distribution of risks for each receptor by allowing some of the parameters in the analysis to vary over a range of values. A probabilistic analysis captures the variability in biosolids application practices and the differences in the environmental settings in which biosolids may be land-applied. The purpose of the document was to provide a "high-end" estimate of exposure and cancer risk to an individual farmer and his family from the application of sewage sledge to agriculture land. The estimate of risk is to be used to establish concentration limits for dioxin in sewage sledge that will be applied to agriculture land.

General Comments

I found the document to be well written, easy to understand, and to provide a comprehensive assessment of the risks posed to humans by the application of sewage sludge on agricultural land. The models employed to evaluate the fate and transport of contaminates provide a realistic assessment of the probable concentrations of pollutants at points of human exposure. The models used in this assessment are reasonable and are similar to those used in other EPA assessments and, for the most part, are accepted as state-of-the-art by the scientific community. The atmospheric transport model used is an EPA recommended model that has had widespread application is other risk assessment. The model developed to characterize uptake of contaminants into the food chain (the dominate exposure pathway) is state-of-the-art and has also been used in previous assessments. It is my belief that these methodologies provide an adequate basis for a national level assessment The exposure pathways selected for analysis represent pathways most likely to result in significant human exposure and thus provide a reasonable worse case analysis. The parameters used in the analysis are appropriate. I thus believe that the current document represents a complete and comprehensive analysis of reasonably anticipated high-end exposures and risk from the land application of dioxins and related compounds in biosolids in an agricultural setting.

Response to Issues

Document No. 1 (The Technical Support Document)

Is the selection of exposure pathways scientifically reasonable for appropriate characterization of the exposure evaluation as "high end" within the meaning of EPA's Guidelines for Exposure Assessment?

The exposure pathways considered in the document are reasonable and appropriate for a "high-end" assessment. The exposure pathways selected represent pathways most likely to result in significant human exposure and thus provide a reasonable worse case analysis. The parameters used in the analysis are appropriate.

Is the modeling of the accumulation of dioxins in the soil from the land application of biosolids at several land application scenario sites and the accumulation of dioxins in the subsurface environment from the surface disposal of biosolids, including the half life assumptions of applied dioxins as function of incorporation/burial/stacking depth and application method technically adequate?

The modeling of the accumulation of dioxins in the soil appears to be reasonable and adequate for a national level assessment. All of the important processes effecting the fate and transport of dioxin in soil are considered. The algorithms used to account for the different fate and transport processes are appropriate and the parameters used in the algorithms seem reasonable. The half-life assumptions seem appropriate. Thus, I believe that the procedures followed in the document give a reasonable estimate of "high-end" concentrations of dioxin in soil and other media at likely points of exposure.

Are the exposure pathway algorithms used to estimate dioxins exposure to the population modeled for each of the identified exposure pathways correct and transparent?

The exposure pathway algorithms used to evaluate exposure from the selected exposure pathway are correct and appropriate. The algorithms used are similar to those used in other EPA assessments and are consistent with EPA guidelines.

Are the algorithms used to model the fate of dioxins in biosolids applied to the land and the fate of dioxins in biosolids surface disposed with particular emphasis on bioaccumulation and transport to groundwater algorithms scientifically adequate? (In general, fate pathways include soil-to-air, soil-to-plants, soil-to-plants-to-animals, and subsurface soil to groundwater.)

The algorithms used in this document to model the fate of dioxins in soil, air, food and water are appropriate for a national level analysis. They represent state-of-the-art models for the evaluation of the multimedia partitioning and fate of contaminates in a national level assessment. The soil-to-plants and the soil-to-plants-to-animals algorithms are based on the best of current knowledge and include all of the most important pathways for the incorporation of contaminates into the terrestrial food chain. The parameters used in these food chain algorithms are reasonable and appropriate. The algorithms used to evaluate transfer from soil to air and groundwater are reasonable and appropriate for the type of analysis performed.

Are the selected default values in the exposure pathway algorithms including but not limited to exposure assumptions, fate parameters, bioconcentration factors, decay rates, and all other parameters appropriate for the stochastic modeling runs as will as any deterministic runs performed in the risk assessment?

The default values used in this assessment appear to be reasonable and appropriate and follow EPA guidance on selection of parameters for a “high-end” assessment. While I do not agree with every default parameter selected, the default parameters selected agree with those in other recent EPA documents and have previously undergone peer review. I do agree that the parameters selected are likely to give an over estimate of individual exposure and risk. The stochastic analysis appears to be performed corrected and should provide an reasonable “high-end” characterization of the individual risk resulting form the use of biosolids on agricultural land.

Are the calculations for each of the exposure pathways algorithms performed correctly?

The calculations in the document appear to have been performed correctly.

Document No. 2 (The Risk Characterization)

Based on reference to EPA’s Guidelines for Exposure Assessment:

Do you agree with the risk characterization based upon your review of the exposure evaluation and the risk assessment contained in the Technical Support Document?

Yes, I believe that the document provides a comprehensive assessment of the risks posed to farmers and their families by the application of sewage sludge on agricultural land.

The reviews will provide specific language to EPA on their characterization of the risk assessment, e.g. “high end”, “bounding”, “central tendency”, etc.

I believe that the risk assessment performed represents a “high-end” exposure and individual risk. Not only is the farm family assumed to live on the farm, but also it consumes a large fraction of its diet from farm grown food, an unlikely event. It may be that a farm family consumes a high fraction of some diet item (like fruit or vegetables) from farm-produced food, but it is very unlikely that any farm family obtains large fractions of all diet items (fruit, vegetables, meat, milk, chicken, eggs, fish, etc.) from their farm. Thus, this exposure scenario represents a “high-end” exposure. In addition, all reasonable exposure pathways are evaluated and high-end exposure parameters are used in the evaluation. Thus, I believe this risk assessment represents a “high-end” assessment of the risk of agricultural application of sewage sledge.

Document No. 3 (Estimate of Population Modeled and Annual Cancer Cases from the Modeled Population)

Are the assumptions that are stated in the estimates reasonable?

I believe that both the estimated size of the exposed population and the number of annual cancer cases are over estimates. U.S. Census data indicate that within the U.S. population of 2.8 x 10+8 individuals, about 2 percent lives on farms. The document assumes that the entire 2% raise their own crops and animals, and consume a significant portion of their annual diet from their farms. This is highly unlikely.

There are about 1.9 million farms in the United States and 1.56 percent of the U.S. population lived on farms in 1990 (U.S. census data). The 1997 U.S. farm census data show that of the 1.9 million farms, 800,000 produce beef cattle, 116,000 produced milk, and 106,00 have orchards and only 53,000 harvested vegetables (reference given below). These data indicate that concurrent exposure by a farm family to farm-produced meat, milk, fruit, vegetables and home-caught fish is unlikely to occur. An assumption of concurrent exposure to these food items is appropriate in estimating high-end individual exposure. However, in estimating population exposure and risk, this assumption overestimates the exposed population and the number of annual cancer cases.

Are the calculation for the estimated population modeled and the annual cancer cases from this population performed correctly?

The calculations of estimated size of the exposed population and the number of annual cancer cases in this population appear to be performed correctly.

Additional General Comments

Climate Regions. The document does not tell how the climate regions were selected. Were they selected based on fairly uniform soil characteristics or meteorological data within a region, or both? In predicting soil concentrations, which is more important, the soil temperature and amount of rainfall or the soil characteristics? The answer to this question will determine how one would want to select the 41 climate regions.

In performing the analysis, one of the 41 climate regions is picked at random and modeling is done using the characteristics of that region. The process is repeated 3,000 times. This approach gives equal weight to all climate regions in the U.S. However, not all climate regions have the same number of farms and, consequently, the same number of exposed farm families. The document should discuss this issue and explain why it is not a problem for the current assessment. I believe it is not a problem in estimating the "high-end" individual exposure, but it will produce an inaccuracy in estimating the total population exposure. Nevertheless, some discussion of this issue is needed.

Linearity. In calculating the Risk-Based Waste Concentrations (page 7-10), the text states, "This scaling approach is allowable since all of the modeling results in the analysis were linear with respect to the initial biosolids concentration." However, the document seems to indicate on page 5-17, paragraph 2, that there is a nonlinear relationship between farm size and air concentrations. Page 5-24, paragraph 1 gives a hint that soil concentrations in cold climates may be nonlinear with farm size. This discrepancy needs to be explained.

Nursing Infant. The analysis allows for exposure to an infant via the ingestion of breast milk. The mother is assumed to live on the farm and ingest contaminated food and receive exposure through other pathways, with some of the contamination stored in the fat of her breast milk. The infant is then exposed during nursing. The exposure duration for the mothers averages18.75 years (Table J-14, page J-27). It can be assumed that the concentration of dioxin in breast milk of the mother will increase throughout this exposure. The document does not state at what time during the mother's exposure the infant begins nursing. Is it assumed that nursing begins at the end of the mother's exposure?

Intake Factors. In the section defining the distributions on intake parameters (section 6.2.1, pages 6-7 through 6-29), the document does not use a consistent definition of central tendency and high-end exposures. For example, in tables 6-4 and 6-5, the central tendency for the child is less than the P50 value, while the central tendency for the adult is slightly greater than the P50 value. The high-end intake for the child is less than the P90 value, while the high-end for the adult is greater than the P90 value. Similar problems occur with the other intake parameters in this section. The document needs to define how it is selecting high-end values for children and adults.

Frequently, all the consumption distributions but one are lognormal. It might be better to just use a lognormal distribution for all exposure distributions. This would lead to consistency and simplicity in exposition.

The percentage of consumption that is homegrown sometimes seems too large. For example, it hard to believe that the average farm household produces 32.8 percent of their fruit intake or 25.4% or their dairy product intake or that adult fishers catch 32.5% of their total fish intake (and 64% of T4 fish) in streams near their farms. The document needs to explain that these estimates are only being used to insure that the analysis is a high-end estimate and that it is unlikely that any single family would be exposed to all of these pathways simultaneously.

Groundwater. The document talks about estimating leaching of contaminant from the agricultural fields to groundwater. However, the document never says how important this pathway is, nor does it give a risk estimate for this pathway of exposure in Chapter 7. The document should say that this pathway is only included in the analysis to insure realistic calculation of soil concentrations, but that exposure to ingestion of groundwater is not a pathway of exposure considered in this document. The document might also want to say (if it is true) that dioxin is relatively immobile in soil and does not reach groundwater in sufficient concentration to pose a risk to humans.

Exposition. The document needs to add more information concerning the results of the analysis. How do soil concentrations behave over time, that is, what is the factor of buildup over the lifetime of application? What are the major loss pathways for soil: leaching, volatilization, and degradation? How do buffer zone soil concentrations compare with crop and pasture land? What is the relative importance of air deposition and surface runoff in buffer zone soil concentrations? What are the major food chain pathways for exposure and what is their relative contribution? What are the major pathways of exposure to the farmer? What is the percentage contribution of air, soil ingestion, terrestrial food, and fish to exposure? What is the percentage contribution of the various pathways to total risk? Table 7-12 provides some perspective but it is not sufficient.

Sensitivity Analysis. The introduction and overall description of the sensitivity analysis needs improvement. The description on pages 8-4 through 8-5 and pages K-3 through K-4 will not be understandable by the average technically trained reader.

Specific Comments

Page 1-1, paragraph 3. I think that in addition to the current overview of the purpose of the document, EPA should say that this assessment will look at risk from a national perspective and attempt to provide a characterization of the high-end of the nationwide probability distribution of individual risks resulting from application of biosolids to agricultural fields.

Page 2-1, paragraph 1, last sentence. It is not clear what the document means by the statement, "The cancer slope factors for all of the dioxin, furan, and polychlorinated biphenyl congeners considered in this analysis are based on the toxicity of the most highly characterized congener, 2,3,7,8-TCDD." Does this mean the slope factor for 2,3,7,8-TCDD was used for all other compounds or that a toxic equivalent method was used that based the cancer potency of the other compounds on that of TCDD?

Page 2-1, paragraph 2. The document says, "The cancer slope factor for 2,3,7,8-TCDD used by EPA in this and other recent assessments is 1.56×10^5 $(mg/kg/day)^{-1}$." This risk factor differs from EPA's more recent cancer slope factor for TCDD in U.S. EPA 2000.

Page 2-2, section 2.1.1. This section is well written and clear.

Page 2-4, paragraph 2. The document says, "…all provide support for an association between exposure to dioxin and related compounds and increased cancer mortality." This statement seems overly strong. There is no doubt that TCDD is an animal carcinogen. However, EPA concluded in EPA 2000 that the epidemiological evidence for TCDD carcinogenicity is inconclusive.

Page 2-6, paragraph 2. The document says, " 2,3,7,8 TCDD …is described as potentially multisite carcinogens in the more highly exposed human populations…" As this document points out on page 2-1, paragraph 1, "EPA characterizes 2,3,7,8 TCDD as a "human carcinogen"", Thus why do you say it is "potentially" a multisite carcinogen?

Page 2-6, paragraph 3. I am in agreement with this paragraph.

Page 2-6, paragraph 4. The document says, "TCDD is characterized as a multistage carcinogen because it increases the incidence of tumors at sites distant from treatment sites and at does well below maximum tolerated dose." What does increasing the incidence of tumors at sites distant from treatment sites and at does well below maximum tolerated dose have to do with showing TCDD is a multistage carcinogen?

Page 2-6, paragraph 4. The text says, " The strength of this association is understood by the fact …" This sentence is unclear. The strength of what association? How do positive bioassays help in the understanding of an association? They may strengthen an association, but they do not increase understanding of the association.

Page 2-7. I agree with the statements on page 2-7.

Page 2-10, paragraph2. This clarifies the use of the risk factor on page 2-1.

Page 3-1, paragraph 4. I like the approach of subdividing the United States into 41 climate regions assumed to be uniform in climate. At this point the document does not tell how the regions were elected. I assume that explanation will come later.

Page 3-5, section 3.1.5.1. Since a lactating wife was mentioned on page 3-2, I assume that a lactating mother is also assumed to be a human receptor.

Page 3-5 section 3.1.5.2. The exposure pathways considered are appropriate.

Page 3-6, section 3.1.7. The method presented for calculating protective biosolids concentrations seems reasonable.

Page 3-6, section 3.2. The text says, "The primary methodology for this assessment was to estimate risk using a probabilistic approach." First, I think this sentence should say, the primary objective for this assessment was to estimate risk using a probabilistic approach. Second, the section should be clearer as to what the probability distribution is describing. For example, that it is the probability distribution of the risk from exposure to TCDD in sewage sledge to an individual (or certain receptor type) drawn at random from the United States.

Page 3-6, section 3.2.1. A Monte Carlo simulation is the correct manor of performing this analysis.

Page 3-7, paragraph 2. The text says, "…locations were first selected at random with equal probability of occurrence based on the 41 climate regions." It would seem that if one really wanted to obtain a probability distribution of risk representative of the United States, one would have to select the locations using a population weighted probability. The 41 geographic regions have different total populations. If one wants the final individual risk distributions to be representative of the United States, these different populations totals need to be taken into account. Using a population weighting to select the geographic location will also provide a population weighting on the climate and soil parameters.

Page 3-7, section 3.2.2. The method outlined in this section seems reasonable.

Page 4-1, section 4.2. It is not clear what the document means by "Biosolids in this risk assessment were assumed to be characterized by a single distribution of physical and chemical characteristics." What does the phrase "single distribution" mean?

Page 4-1, section 4.2. This section should have a sentence that explains how one combines these parameters with those of agricultural soil where the biosolids are applied to soil.

Page 4-2, Table 4-1. A single number is used to characterize the fraction of organic carbon. One would think that this is a sensitive parameter and should be characterized by a distribution.

Page 4-2, section 4.2.1. This section is clear. Two important assumptions are made in this section: 1) the frequency with which a facility is selected is weighted according to the quantity of biosolids produced by the facility, and 2) when congener concentrations are below the minimum detection limit, a concentration equal to half of the detection limit is assumed. I agree with both of these approaches.

Page 4-3, section 4.2.2, last sentence. The document says, " Application rates for biosolids were not associated with location in this analysis." This sentence could be made clearer. You might say, For this analysis, application rates were assumed to be uniform across the nation.

Page 4-4, section 4.3.2. The document says, "The boundaries of the climate regions used in this analysis were drawn to circumscribe areas that could be represented by a single set of climate data." The document is not clear as to what climate data were important in selecting the 41 climate regions. Was rainfall the only variable used, or were temperature and wind speed also used?

Page 4-5, Table 4-2. It is not clear how farm size is used in this document. On page 4-4, paragraph 2, the document says the agricultural field area of the general site layout, as shown in Figure 3-1, is assumed to be the median area for farms in each climate region. But how does farm size affect the analysis? I assume that it effects the environmental partitioning (and maybe the total source term), but if so, the document should have a sentence indicating this so that the reader has a better idea of what is going on.

Page 4-6, paragraph 1. How were the meteorological station selected to represent each of the 41 climate regions? Since on page 4-7, land use percentage around each meteorological station is used to estimate meteorological parameters, how the meteorological stations were selected might affect the analysis.

Page 4-6, paragraph 1. The document says, "Each climate region was equally weighted in the probability analysis." I'm not sure that this is the correct to perform the analysis. One might think the climate regions with greater population would be weighted more heavily. Why is this not the case?

Page 4-6, section 4.3.2.1. How were hourly surface meteorological data used in the Monte Carlo analysis?

Page 4-7, paragraph 1. The document says, "…the station was discarded and another nearby station was selected to represent the site." The replacement station does not have to be a nearby station, just another station in the same region.

Page 4-7, last paragraph. Since land use information is important, I would think EPA would find the land use information around each meteorological station in a climate region and then average them to obtain a land use profile for each climate region. It appears from the description that EPA selected a single meteorological station within a climate region as the basis for determining land use patterns. If the meteorological station selected was near an urban area, the land use patterns might not be representative of rural areas.

Page 4-12, section 4.3.2.3. It is not clear if probability distributions or point estimates were used for the soil types within a climate region.

Page 4-12, section 4.3.2.3. The document says, "Soil properties are listed by data source and model in Appendix E." This sentence is unclear. First, appendix E does not contain soil types. Second, what does listed by model mean? There is no mention of models in appendix E.

Page 4-16, Table 4-9. It is not clear what the titles of the columns mean. For example, what do Ksat, WCS, RHOB, and SMb mean?

Page 4-18, paragraph 2, first bullet. The text says, "Table 4-9 presents the mean value for field capacity (SMFC) by hydrologic soil group…" The symbol SMFC does not appear in Table 4-9.

Page 4-18, paragraph 2, second bullet. The text says, "Table 4-9 lists the mean value for wilting point by …" The symbol SMWP does not appear in Table 4-9.

Page 4-20, paragraph 2. There is a typo in this paragraph. The text says, Censue of Agriculture (U.S. DOC, 1989, 1996). It should say, Census of Agriculture.

Page 5-2, section 5.1.1.1. The text says, "The sheet-flow-only restriction is based on the assumption that any area downstream …" The document is not clear as to what the sheet-flow-only restriction is. Does that mean that the only way pollution enters downslope areas is through overland flow?

Page 5-4, section 5.1.1.2. I agree with the first three assumptions used in the LAU model. They are standard and reasonable. With regard to the last two assumptions, it is not clear if the first-order loss rates from soils are used only as a source term to air or if they also result in loss of contaminate from soil. The forth bullet says it is possible for immobile constituents to build up in the soil. However, it is not clear if this is because the application rate is greater than the first-order soil loss rate or if it is because if the first-order loss rate is not used to deplete soils of their contaminates.

Page 5-5, equation 5-1. This equation answers my immediately preceding question, but I still think you should make the point clear in the text on page 5-4.

Page 5-5 and 5-6. The explanation of how equation 5-1 is solved is clear and seems to be a reasonable approach. The use of a 200-year time limit is a risk management assumption, but seems reasonable. I certainly would not use a longer time period without good justification because of the increase in uncertainly that comes when modeling over long time periods.

Page 5-7, equation 5-3 and 5-4. These are standard equations and are appropriate. The implication that the soil column sportive capacity does not become exhausted is important to point out. However, for dioxins, which will be immobile in the soil and thus build up, this may lead to unrealistic conditions in the soil. Do soil concentrations of dioxin stay low enough in soil over time that the linear assumption (equation 5-3) seems reasonable?

Page 5-7, third to last bullet. The text says, "The total chemical flux is the sum of the vapor flux and the flux of the dissolved solute." What about chemical loss from soil due to wind erosion, vehicular activity, and tilling operations?

Page 5-7, bullets. All of these assumptions seem reasonable and standard.

Page 5-9, paragraph 1. Pointing out that no enrichment for small particles is assumed is good. This assumption seems reasonable.

Page 5-9, paragraph 2. The document says that validation was not carried out because the sites modeled are hypothetical. This does not seem like a valid reason. The only thing hypothetical about these sites are the exposure scenarios. The soil properties, meteorology, hydrology, etc are real. Thus, validation could theoretically be carried out. However, the real reason validation cannot be done is that you need real date from real sites to do validation. Such data are not available for all the components of this modeling effort. However, some components of the modeling approach have undergone validation, for example, the atmospheric component.

Page 5-10, paragraph 1. It would be interesting if the document gave the primary soil loss mechanism leading to the observed TCDD half-life in soil. I assume that it is volatilization, as opposed to soil leaching or particle loss from the soil surface.

Page 5-10, Table 5-1. These soil-loss half-times indicate that the 200 years used in the simulations (page 5-6, paragraph 2) is more than adequate. What is the source of the variability in half times? Is it the variability in soil and metrological conditions across the U.S.?

Page 5-11, paragraph 1. The document says, "These observed half-times seem to corroborate the range of half-lives resulting from the source model funs, thereby affording a measure of credibility to the modeled results." This exercise, which I highly indorse, says little about the validity of the individual model components. It does tell you that you have the rate coefficient for the dominant loss term from soil about right. That gives you some confidence that estimated soil concentrations are not too low. While this exercise in calculating TCDD half time in soils does not validate the models, it is still highly informative and I am pleased that it was included. It is a good reality check to see if the model is running in a reasonable way. The modelers are to be congratulated for including it. It would be nice to include other calculations, like partitioning percentage of TCDD in soil verses soil water and compare that with field data.

Page 5-12, section 5.2.1.1. I agree with the use of the ISCST3 model for this exercise. It is a standard EPA model that has been used extensively in regulatory applications. It has received widespread review during previous applications.

Page 5-13, paragraph 2. This is a good description of the ISCST3 model. The paragraph says, "…vertically according to a Gaussian distribution, which is similar to a normal distribution." You might want to say, "according to a Gaussian distribution, which is another name for a normal distribution."

Page 5-13, section 5.2.1.2, paragraph 2. The use of unit values for air concentrations and deposition rates is standard and appropriate.

Page 5-14, paragraph 3. Pointing out that depletion of vapors from the plume was not considered is appropriate. This should not have a large effect of modeled air concentrations.

Page 5-15. The descriptions given on this page are clear and appropriate.

Page 5-16, TOXICS vs. Regulatory Mode. It is appropriate to use the TOXICS mode in this assessment.

Page 5-17, section 5.2.1.4. Why would air concentration depend nonlinearly on source area size? You say on page 5-13 that you use unit air concentrations based on unit emission rates. Thus, you assume a linear relationship between air concentration and emission rate. Thus, I can assume that the relationship between farm size and emission rate is nonlinear. Why is this?

Page 5-18, Table 5-3. There are no numbers in this table.

Page 5-18, Table 5-4. How do these air concentrations compare to background air concentrations of TCDD? What percentage of TCDD in air is attached to particulates and what percentage is in vapor form? How does this compare to ambient measurements for TCDD percentages in air? This point is important because it influences how much dioxin is taken up in vegetation through air-to-plant transfer. Presenting these ratios provides another check on the validity of the modeling results.

Page 5-18, last bullet. What is the most important meteorological parameter, temperature? The examples given on page 5-19 of the highest 1 percent air concentration seem to support this view.

Page 5-19, section 5.2.2. This section is clear.

Page 5-22, Table 5-5. There are no numbers in this table.

Page 5-23, Table 5-6. This table is interesting. I am surprised that the soil concentrations in pasture are only about 4 to 5 times greater that the soil concentrations in cropland given that inputs are mixed to 20 cm for cropland and only 2 cm for pasture. Why are not soil concentrations linear with initial concentration, which is 10 times greater for pasture than cropland?

Another surprising thing is that Buffer soil concentrations are higher than cropland. I guess this is because buffer soil concentrations are an average of input from cropland and pasture. Or is it that runoff from cropland builds up on the surface of the buffer zone? The document should be clear on this. This brings up another question. What is the mixing depth in the buffer zone?

What is the largest contributor to buffer soil concentrations, upland runoff or atmospheric deposition?

How do these soil concentrations compare to background soil concentrations? One would expect them to be higher, but how much higher? How do these soil concentrations compare with the concentrators in the sludge that was applied? In other words, how much buildup is there in soil concentrations over time as a result of biannual application of sewage sludge?

Page 5-23, paragraph 2, bullet 1. The text says, “the year during biosolids application that the farm family moves to the farm.” I do not see how the year the farm family moves to the farm can affect the dioxin congener concentration in the soils. The dioxin soil concentrations are affected by other variables. It is the magnitude of exposure of the farm family is affected by when they move to the farm.

Page 5-23, last paragraph. This is a good addition to the document, but it only explains why exposure depends on when the farm family moves to the farm, not why soil concentrations depend on when the farm family moves to the farm.

Page 5-25, paragraph 1. The text says, “The soluble fraction are so low that they are assumed to be zero.” It is not clear what this means. Does it mean the solubility of the contaminates in water is so low that the model assumes zero solute in water?

Page 5-27, table 5-7. This table mentions vapor-phase deposition while equation 5-10, page 5-28, mentions air-to-plant transfer. Are they the same thing?

Page 5-30, Table 5-8. There are no values given in Table 5-8.

Page 5-31, Table 5-9. How do the concentrations given in Table 5-9 compare with background TCDD concentrations is fruits and vegetables?

Page 5-32, Table 5-10. There are no values in this table.

Page 5-34 and 5-35. Equations 5-14 and 5-15 appear to be correct.

Page 5-36, Table 5-12. There are no values in this table.

Page 5-36, Table 5-13. How do these values compare with background TCDD concentrations in beef?

Page 5-37, Table 5-14. There are no values in this table.

Page 5-37, Table 5-15. How do these values compare with background TCDD concentrations in milk?

Page 5-38, Table 5-16. There are no values in this table.

Page 5-39, equation 5-16. This equation appears to be correct.

Page 5-41, Table 5-17. The ratio between the 95^{th} percentile and the 50^{th} percentile concentration is 4.05 for poultry thigh meat, while it is 4.5 for beef and 4.8 for milk. Why is the probability distribution for TCDD concentration in poultry thigh meat different than that for beef and milk? Is this simply due to statistical variation in the Monte Carlo method?

Page 5-41, Table 5-18. There are no values in this table.

Page 5-42, Table 5-19. The ratio between the 95th percentile and the 50th percentile concentration for eggs is 3.8. This is even farther off than poultry thigh meat. Can the difference depend on the fact that poultry thigh meat and egg concentrations depend mainly on soil concentrations, while beef and milk concentrations depend mainly on air vapor concentrations, and that the distributions for air vapor concentrations are slightly wider that those for soil concentrations due to greater differences in temperatures across the U.S.?

Page 5-43, equation 5-18. This equation appears to be correct.

Page 6-2, section 6.1. The receptors and exposure pathways in Table 6-1 appear appropriate.

Page 6-4, section 6.1.3. The exposure pathways listed in this section are appropriate.

Page 6-5, ingestion of breast milk. The document does not say how long adult women farmers are exposed (how long they live on the farm) before they give milk to the infants. The document also does not say how long infants consume breast milk. I assume these details are coming later.

Page 6-7, section 6.2.1.1. The document says, “Thus, soil ingestion rates used in the probabilistic analysis were not varied for any age group.” The meaning of this sentence is not clear. It would be clearer to say, “Child soil ingestion rates were used for children in the age group 1 to 5. Adult soil ingestion rates were used for all other age groups.” Since this section does not say, I assume a fixed value was used for the soil ingestion rate as apposed to a distribution. This point should be made clear.

Page 6-8, Table 6-4. It is not clear if these distributions are appropriate. How was the fraction of exposed fruit intake that is home-grown used in obtaining this table? Does one first obtain the distribution for each age group using Table 13-61 of the EFH (U.S. EPA, 1997b) and then multiply by 0.328 for households that farm and 0.116 for households that garden? How do you know that P90 and P95 exposures do not exceed what is reasonable given the average (or maximum) fruit intake of a normal person and the fact that only a fraction of fruit intake comes from the farm?

I find it hard to believe that the average farm household produces 32.8 percent of their fruit intake. The most common fruits eaten by people are bananas, apples, oranges, and peaches. These are not grown on the average farm. Thus, they will not be home grown on most farms. Farm households do produce watermelon, cantaloupes, and berries, but I doubt that these makeup 32.8 % of farm family intake of fruit. Another question is, what percentage of farm families do not produce any fruit on their farm? Many farms that people live on only produce cattle or dairy cows. If they do have a garden, they do not grow apples, oranges, bananas, peaches, etc. Small gardens are usually for vegetables, but not fruit. And at least some fraction of farms would grow no fruit in their gardens. This kind of information should be available for the Department of Agriculture. A quick search found that Virginia has 49,000 farms, but only 751 that produce fruits, nuts and berries. Thus, only 1.5% of Virginia farms grow fruit, but the current assessment assumes that 32.8 percent of fruit intake is homegrown for households that farm.

On page 6-3 the document says, the reason for considering children separately is that they consume more per unit body weight. However, Table 6-4 shows the mean intake of a 1 to 5 year old child to be about the same as an adult. If anything, these numbers show lower intake for children (the 12 to 19 age group).

In Table 6-4, is the mean the best way to characterize the "average" distribution value? Since these are lognormal distributions, why not use the geometric mean?

What does the Max mean in table 6-4? Are the distributions truncated at the value given by Max?

Page 6-9, Figure 6-2. What does the black triangle mean in these figures? It does not correspond to the Max value given in Table 6-4, thus it's meaning is not clear.

Page 6-9, Table 6-5. What is the basis for the central tendency number in this table? The adult central tendency is 1.36 as compared to a mean of 2.36 in Table 6-4. What is the statistical definition of the high-end exposure? It does not appear to be either a 90th or 95th percentile (as defined in Table 6-4).

Page 6-10. I have the same questions about Table 6-6 and Figure 6-3 and Table 6-7 that I had on the tables and figures in the previous section. At least for vegetable consumption, children 1 to 5 are consuming more on a per weight basis than adults. The high end exposure for the child and adult in Table 6-7 appears to be less than the 90th percentile in Table 6-6. Why is this?

Page 6-11. I have the same questions about Table 6-8, Figure 6-4, and Table 6-9 as before. The high-end exposure for adults in Table 6-9 is the 90th percentile. Why in this case but not the others?

Page 6-15, Table 6-12. The text says that CSFII data were used to generate the dairy consumption distributions. If this is so why are the distribution characteristics filled in in Table 6-12 for the HP and EFH(HP) data, but no the CSFII data?

It is not clear what Population Estimated Scale means in Table 6-12.

Page 6-16, last sentence. The text says that 25.4% of farm households consume home-produced dairy product. I do not believe that 25.4% of farm households in the U.S. raise dairy cattle and obtain their daily products from them. For one thing, many parts of the country, like the southwest, are not particularly conducive to growing dairy cattle. There are about 2 million farms in the United States and only about 100,000 are licensed to produce milk. This means that less than 5% of farms in the United States are licensed to produce milk. A quick search found that Virginia has 49,000 farms, but only 1,296 that produce dairy products. Thus, only 2.6% of Virginia farms produce dairy products, but the current assessment assumes that 25.4 percent of dairy product intake is homegrown for households that farm.

Page 6-17, Table 6-13. The central tendency numbers in this table seem too high. They are greater than the 95th percentile in Table 6-12. For instance, the central tendency for adults is given as 12.6, while table 6-12 lists the 95th percentile as 9.88. How can the central tendency be larger than the 95th percentile? Also the high-end numbers also appear high. For example, 90.2 for the child is off the scale of anything that appears in Table 6-12. Same for the adult.

Page 6-19, paragraph 1. The fraction of poultry that is home produced is 0.156. This number seems more reasonable than the 0.254 for dairy products. If anything, the poultry number of 0.156 calls into question the dairy number of 0.254 because chickens are much easier to grow on a farm than dairy cows.

Page 6-19, Table 6-15. The central tendency and high-end numbers in table 67-15 do not match with the numbers given in table 6-14.

Page 6-22, paragraph 1. It is hard to believe that adult fishers catch 32.5% of the fish they eat close to their own farm. It is harder to believe that they catch 64% of the T4 fish they consume close to their own farm.

Page 6-23, paragraph 1. The use of a triangular distribution is reasonable.

Page 6-23, Table 6-21. Why is the central tendency in this table given as 687, while in Figure 6-10 and in Table 6-20 it is given as 688? How can the high-end consumption be the same as the central tendency, while figure 6-10 shows a high-end consumption of 1,376?

Page 6-30, paragraph 1. The approach to averaging time seems reasonable.

Page 7-2. Table 7-1 has no data in it.

Page 7-3, soil ingestion. It is not clear if the soil for the soil ingestion risk assessment was taken from the buffer zone (where the farmer is assumed to live) or from the crop production area. The buffer zone would be more appropriate. It is not clear if the elevated soil concentrations resulting from many years of application were used or if the soil concentration resulting from one application was used.

Page 7-4, section 7.1.3.2. These calculations appear to be appropriate and correct.

Page 7-7, paragraph 1. Why are the 90th percentile risk levels given for beef, but the 95th

percentile risk levels are given for poultry and eggs? This inconsistence makes it appear as though the document is trying to understate the risk from beef consumption. The same is true for milk in section 7.1.3.6.

Page 7-10, Table 7-11. These risks seem low. I thought breast milk ingestion was a high-risk pathway for exposure. In the Dioxin reassessment, EPA found high risk from this pathway from background exposures. Why does it turn out to be low in the case of sewage sledge application?

Page 7-10, section 7.2. You should restate the target risk level. I assume it is 1.0 E-5.

Page 7-10, section 7.2.1. The text says, "This scaling approach is allowable since all of the modeling results in the analysis were linear with respect to the initial biosolids concentration." I don't believe that this statement is true. The document seems to indicate that air and soil concentrations are nonlinear with farm size, as indicated on page 5-17, last section and page 5-24, paragraph 1. This point needs to be made clear in the document.

Page 7-10, equation 7-2. The use of equations 7-2 and 7-3 is correct and appropriate.

Page 7-11, table 7-12. There are no numbers in this table.

Page 7-12, section 7.3. The description of the probabilistic approach taken in this section is not adequate. More detail needs to be given as was done in section 4.0 of this document. It is not clear how a distribution of concentrations for dioxin in sewage sledge was obtained. Nor is it clear how the distribution was applied to arrive at risk. Were distributions of sewage sledge concentrations used along with distributions of exposure factors to arrive at a totally probabilistic approach to calculating the actual risk associated with current concentrations of dioxin in sewage sludge?

Pages 7-13 through 7-16. Why are the risks using this method of calculation (I guess this method is using the actual distribution of concentrations of dioxin in sewage sledge rather than a single concentration, but it is not clear that this is the case) lower than the risks obtained using a single sample (section 7.1)? Was the sample selected in section 7.1 at the upper end of the distribution of measured concentrations in sewage sledge?

Page 8-1. This page is clear.

Page 8-2, paragraph 5. The document says, "However, uncertainty about farm size within a climatic region remained." If you want to be consistent with your own usage of terms, it is not uncertainty that remains, but variability. Thus the sentence could say, "However, variability of farm size within a climatic region was not characterized."

The paragraph also says, "Distributions were used to capture nationwide variability in agricultural practices." What is this sentence referring to? What farm practices, sewage sledge application rates? What else is there that you used distributions for?

I assume that one of the 41 climate regions was picked at random and them the rest of the modeling was done on the characteristics of this region and that this process was repeated 3,000 times. This approach gives equal weight to all climate regions in the U.S. However, choice of climate region for each iteration should have been by the number of farms in that region.

Page 8-3, section 8.1.2.1. I agree that use of the 41 climate regions provides a reasonable representation of the variability in meteorological conditions in the Untied States.

Page 8-4, section 8.1.2.5. I agree that probabilistic approach used in this assessment provides a reasonable approach to assessing the risk for dioxins, furans, and PCBs in biosolids. I believe that the EPA has made an excellent effort to capture most of the variability present in exposure to biosolids. Also when uncertainties existed in the variability, EPA tended to overestimate upper end exposures.

Page 8-4, section 8.1.2.6, paragraph 1. This paragraph is not very clear. There must be a clearer way the describe what a response surface is. The paragraph says, "This methodology is referred to as a response surface regression approach because it uses models characteristic of those used in a response surface experiments." This sentence is not clear. What does it mean to "use models characteristic of those used…" What models?

The text also says, " The terminology "response surface" derives from the fact that a regression model involving a number of continuous independent variables can be viewed as …" How does a regression model fit into a sensitivity analysis? There is not enough detail in your description for the uninitiated to follow what you are saying.

The text also says, "The complexity of the model (e.g., whether it contains only first-and second-order terms…" What model are you talking about, the "model estimation methodology", "the regression model", or "the environmental transport and exposure models" used in this document?

Page 8-4, section 8.1.2.6, paragraph 2. The text says, "This methodology is one of the recommended methods for conducting a sensitivity analysis based on the results of a Monte Carlo analysis." Why does the sensitivity analysis have to be based on the results of a Monte Carlo analysis? I thought that the sensitivity analysis could be done independent of the Monte Carlo analysis.

Page 8-4, section 8.1.2.6, paragraph 3. The text says, When the risk depends on the aggregate impact…may not necessarily identity the most important one." What does the "one" refer to?

Page 8-5, entire page after the bullets. This entire section is written poorly and is very unclear.

Page 8-6, paragraph 3. The text says, " FMSS = model sum of squares for the final model" What does the sum of squares for the final model mean? How is it defined? What model are you talking about, the regression model or the original model?

Similarly, the text says, "ERSS = model error sum of squares" How is the model error calculated?

The text says, "The two parameters responsible for the largest percentage of the risk are the two parameters set to high-end values in the deterministic analysis." For all of the exposure parameters, the high-end values were defined in tables given in Chapter 6. What is the above sentence referring to, the environmental transport part of the analysis?

Page 8-7, third bullet. The text says, "Develop a model for Log (environmental concentration) based on the results of the regression analysis." What kind of model, regression model as defined by equation 8-1?

Page 8-8, paragraph 1, equation 8-4. This equation makes clear that when the document talks about a model in many places above, it is talking about the model to produce the environmental concentration. This point should be made clear earlier. It would make things easier to understand.

Page 8-8, bullet. The text says, "Because the final model will most likely contain first- and second- order terms involving…" What is the term "final model" referring to? To often in this section on sensitivity testing the document refers to a model without stating what model is being referred to. This is confusing for the reader. This entire section needs to be written more clearly.

The text says, "FMSS = model sum of squares for full model containing all significant terms" What is the full model? Are you referring to Equation 8-4 with the log (environmental concentration) term replaced by the regression model? These things need to be made clear. For example, you could say at the end of paragraph 1, "Hence forth, Equation 8-4 with the log (environmental concentration) term replaced by the regression model of input variables will be called the full model." I would not use the term "final model" here (see comment above).

The text says, "RMSS and RMDF = model sum of squares and degrees of freedom for reduced model." What does model sum of squares mean? What does model degrees of freedom mean? What is reduced model?

The text says, "FMDF = model degrees of freedom for full model." What does model degrees of freedom mean? What is the full model?

The text says, "The full model refers to the model containing all significant terms in the final log (risk) model." This sentence would be clearer if the document used the definition of full model given above. As it is, it uses the word "model" in three places with different meanings.

Page 8-9, paragraph 4. The text says, "These are reasonable assumptions; however, much uncertainty is associated with the scenario." Give some examples of uncertainties associated with this scenario. You might say, for example, "Some farms may only have cropland, some farms may only have pasture, some farms may not have a stream, and in some farm situations the family may live up gradient from the cropland and pasture. However, the scenario chosen is believed to represent a reasonable bounding scenario for evaluation of the farm application of sewage sledge."

Page 8-10, Table 8-1. This table is interesting and a positive addition to the document. However, since exposure duration, consumption rate, and application rate show up in nearly every pathway, the table does not provide much information about the physical parameters that are important in the modeling effort. It would be beneficial to add two more parameters to each pathway (this may necessitate expanding the table to two pages) so that other important parameters could be identified.

Page 8-11, section 8.2.1.5. While background dioxin exposures may vary over the United States, the dioxin reassessment document gave a good characterization of background risk from dioxin.

Page 8-12, paragraph 3. This paragraph and Figure 8-1 are good additions to the document.

Appendix C.
The parameters in this appendix appear to be reasonable and well documented. They appear to be appropriate for the scenarios being modeled and for a national level assessment. The parameter effdust used a normal distribution to describe its variability. A triangular distribution would have done just as well. It is not clear what the parameters zava (Upper depth average soil concentration) and zavb (Lower depth average soil concentration) refer to. The format of this table is excellent. It provides a concise overview of the parameter values, their variability, and documentation.

Appendix D.
Parameters in Table D-1 appear standard and appropriate for this assessment.

Page D-5. The assumption of zero degradation and hydrolysis is appropriate, but means that very little dioxin is lost from soil after application.

Page D-5. The assumption of a 0.6 fraction of wet deposition adhering to plant surface and a plant surface loss coefficient for particulates of 18.07 1/yr means that about 60% of dioxin in air is transferred to plants during rain events. This seems somewhat high, but I have no data to indicate otherwise. It would be nice if the document would tell what percentage of dioxin taken up by exposed plants is from deposition and what percentage is from vapor air-to-plant transfer. It is generally believed that vapor air-to-plant transfer is the dominant pathway, although little actual data are available.

The chemical-specific parameters given in Tables D-2 through D-30 appear appropriate.

Table D-3. The bioconcentration factor for cattle and poultry, and the biota-to-sediment accumulation factor seem low. The organic carbon partition coefficient for this chemical is higher than for the chemical in Table D-2, but the above parameters are lower.

Table D-5. The bioconcentration factor for poultry seems low. It is lower than the bioconcentration factor for beef. For all other chemicals in this section, the bioconcentration factor for poultry in higher than the bioconcentration factor for beef.

Table D-10. It does not seem appropriate to use two significant figures (2.69) in the value for the bioconcentration factor for cattle. This number should be given as 2.7. This same use of too many significant figures occurs in several of the tables.

Table D-14 and D-15. It is not clear why these two chemicals have the same organic carbon partition coefficients, the same soil water partition coefficients, the same air-to-plant biotransfer factors, and the same bioconcentration factors for cattle, but different bioconcentration factors for poultry and eggs. I realize that the reference given is the 2000 dioxin reassessment, which is suppose to be the most up to date document on dioxin and its properties, but this discrepancy does not make sense.

Appendix E.

The parameters in this appendix appear to be reasonable and appropriate. However, without checking the original references, it is impossible to tell if they are correct. The farm sizes appear large. That is because they represent average size farms and farm sizes have increased over the years as farms become more commercial rather than family owned. It is probable that these farms sizes over estimate the size of farms that actually have farm families living on them. However, using these farm sizes should provide a conservative estimate of the risk of using sewage sledge on farmland.

Appendix F.

Page F-1. The document says, " A source term module was developed for land application units (LAUs) to provide estimates of annual average surface soil constituent concentrations and constituent mass emission rates to air and ground water." The end of this sentence should say "…constituent mass emission rates to air, downslope land, surface streams, and ground water."

Page F-3. This approach to estimating contaminant partitioning into the solid, liquid, and gaseous phases of soil is reasonable and appropriate for the scale of assessment being performed. This is a standard approach to modeling soil concentrations and is widely used in the assessment area. This approach also accounts for leaching of contaminate downward towards ground water due of rain water infiltration.

Page F-6. It is not clear why the effective solute convection velocity (Ve) is equal to

$Ve = 1/K_{TL}$. Why does not the infiltration rate (I) inter into this calculation? (I now see that it is an I in equation 2-10 and not a 1. This should be made clear to avoid confusion.)

Page F-7, paragraph 2. The quasi-analytical approach introduced a tradeoff between the ability to evaluate short-term and long-term concentrations. The approach allows evaluations of long-term concentrations, but not short-term concentrations. This is appropriate for the assessment at hand since dioxin is relatively immobile in soils and builds up over time. Thus, the long-term focus is appropriate.

Page F-7, section 2.4.2. This section is a good addition to the document, but I'm not sure how much new insight it adds to reader understanding. It is probably too mathematical for the average reader. The most interesting sentence is on the bottom of page F-10 and says, "While the contaminant mass in the gas phase volatilizes out the surface of the soil column, the contaminant mass in the aqueous phase is left behind..." I'm not sure this is what actually happens. One would think that volatile contaminate would evaporate along with soil water.

The introduction to this section does not provide a good understanding of how the sequential solution to the three-component differential equations works. Is each of equations 2-13,2-14, 2-15 solved in sequence and then added together? How can convection be done before first-order decay? Without the decay term calculated, the concentration of contaminate in a layer would be too high and the convection equation (equation 2-14) would convect too much contaminate out of the layer. Or does this not mater because the errors are small? The document needs a few sentences to explain this. (I now see that you have an explanation on page F-13, but some introduction is need here since many readers will not look at the detail of section 2.4.2.2).

Page F-11, paragraph 5. The text says, "This component of numerical diffusion can be avoided completely if the contents of each layer are transferred completely to the next layer at the end of each time step…" The meaning of this sentence is not clear. Is the total content of each layer transferred or just the amount that is supposed to be convected? It does not make sense that everything in a layer would be convected out of that layer with each time step. It is also not clear making the time step equal to the layer thickness divided by the effective velocity solves the problem. You need a little more explanation.

Page F-14, section 2.5. This is a good addition to the document.

First Bullet. The text says, "This complexity is not modeled by the GSCM for metals partitioning; rather Kd is externally provided as a randomly sampled value…" This makes it sound like this is a procedure followed just for metals to over come the problem with Kds for metals. Isn't this same procedure done for organic chemicals also?

Second Bullet. I agree that under normal conditions of land application, you should not have pure contaminate (precipitate) present. However, it is good that the model checks for this.

Page F-16, paragraph 2. I agree that the assumption of sheet-flow only is reasonable.

Page F-16, paragraph 3. This is the first time in the document that there is mention of multiple subareas downslope from the LAU. How are they used in the analysis? It is assumed that the farmer lives in the buffer zone. Which subarea of the buffer zones does he live in? What is the purpose for having multiple subareas? Why no just have one long buffer zone? There must be a reason for going to these extra trouble, but the document does not explain it.

Page F-19, paragraph 1. CN is not defined. I can guess that CN means curve number. What is a curve number? What does, "and initial abstraction as a function of storage", mean in the first sentence?

Page F-20, last paragraph, psuedo-code. The text says, "Cneff = area-weighted composite Cni for all subareas" From Table 3-1, CN only appears to depend on soil moisture (although, one would think it would also depend on soil type, but if so, the text does not explain this). Assuming CN only depends on soil moisture, why would the soil moisture conditions for the different subareas be different, they are all right next to each other and thus would receive the same antecedent moisture conditions?

Page F-24, equation 3-19. The document does not explain how the slope angles are chosen. Do they change for each subarea? Are they the same for all subareas? Are they chosen at random from a distribution or are they constant throughout the application?

Page F-26, section 3.3.3. The document does not explain where the K,C,P values come from. Each farm is located within one of the 41 climate regions. Are the K,C,P values averages for the climate region? If so, how do you get different values of K,C,P to obtain an area-weighted value for all subareas? What about spatial variability of LS? How is that accomplished? How is LS (or the slope angle) made to be representative of the climate region?

Page F-46, section 3.7.2. I agree with the assumptions made in this section.

Page F-60, section B.2. The text says, "The reference air diffusivity…" The symbols in "(Dar)" are hard to read in this sentence.

Page F-66, Table C-1. The terms LF cell and WP are not defined. In footnote C, the text says, "For a description of how results for whole LF are obtained from LF cell results, see Section 4.5" There is no section 4.5 in this report.

Page F-79, section D.2.4. I agree that assuming mixing of the soil column in pasture is a shortcoming of the current approach, but it should not produce a very large error. Moreover, the groundwater pathway is not a major pathways of exposure dioxin and thus, this error is not serious. If groundwater was a more important pathway, another approach could be taken to the modeling pasture soil, but it is not necessary in this case.

Appendix G.

Page G-4, paragraph 2. The use of averages over a 3-km radius appears appropriate. The current assessment is only interested in impacts in the vicinity of the land application site, e.g. the farm family and deposition in the buffer zone.

Page G-4, last paragraph. Assuming zero for the anthropogenic heat flux at the farm locations appears appropriate. It is unlikely that such farms are in highly urbanized locations.

Page G-5 through G-8. The parameters in the various tables appear reasonable.

Appendix H.

The Tables in this Appendix all refer to Appendix K as a source of parameters. This is incorrect. Appendix K is on the sensitivity analysis.

Page H-4. This calculation appears correct.

Page H-5. I found all of these parameters in Table J-2. The formula is more complicated than it needs to be since the assessment assumes the concentration of contaminant in the aqueous phase of maternal milk is zero. Why not just state this assumption and get rid of the corresponding terms in the equation?

Page H-6. The Table states that the value for the fraction of air concentration in vapor phase is given in Appendix D. I cannot find it there. For example, see Table D-2 where there is no mention of this parameter.

Page H-12. The parameter Fv cannot be found in Appendix D.

Page H-13. The parameters Fv and Vdv cannot be found in Appendix D. None of the parameters cited as being in Appendix G can be found in that Appendix. Why not just say calculated by Air Model.

Page H-14. None of these parameters are found in locations cited.

Page H-15. None of these parameters are found in locations cited.

Page H-16. The values for the area of the local and regional watershed are not given in Appendix E, Table E-1, page E-3. There is one watershed area given in Table E-1, but it is not clear if it is for the local watershed, the regional watershed, or both.

Page H-21, I'm not sure that ER, the soil enrichment ratio, is in Appendix J. I could not find it. This needs to be checked. Here reference is made to Appendix E for the total watershed area. How is this parameter related to the local and regional watershed areas mentioned in Table H-2.11 on page H-16?

Page H-25. The soil bulk density is not given in Appendix E.

Page H-30. Bs gives bioavailability of contaminant in soil relative to vegetation, and the parameter is in Appendix I as stated. However, what is the bioavailability of contaminant in vegetative vehicle? I assume from the equation that it is 100%. Why is the parameter Bs defined as the bioavailability of contaminant in soil relative to vegetation rather than just the bioavailability of contaminant in soil? You might want to explain this back in the text.

Page H-31. These equations appear correct.

Pages H-32, 33, and 34. These equations appear correct.

Page H-36, 37, 38, 39, 40. All of these tables mention Appendix K as the source of data. Appendix K is the sensitivity analysis.

Page H-46, 47. These tables have the same problem with Appendix K.

Appendix I.

The values in this appendix appear correct and reasonable. The fraction of diet from feed for beef and dairy used in the analysis make for maximum conditions. The value of zero for the fraction of diet for poultry from feed is reasonable given that it is unlikely the a farm will grow feed for poultry.

In Table I-2, Bs is defined as bioavailability for soil, but earlier (in appendix H) it is defined as bioavailability for soil relative to vegetation.

Appendix J.

Page J-4, last paragraph. I agree with using the two-parameter models instead of the three-parameter generalized gamma model.

The parameters in Table J-1 appear correct and appropriate.

It is highly unlikely that anyone would consume an average of 6.48 g/d of fish, 100% of which is home caught, but this should certainly give a high-end estimate of exposure from this pathway.

Page J-11, Table J-2. The parameters given in Table J-2 appear correct and appropriate.

Page J-12. The text says, "Exposure frequency was set to 350 days per year in accordance with EPA policy, assuming that residents take an average of 2 weeks' vacation time away form their homes each year." U.S. census data indicate that only about 50% of U.S. farmers work fulltime on their farms. The rest have other jobs off of their farms.

However, it is true that somewhere there is the high-end farmer that works 350 days per year on his farm.

The soil ingestion rates used appear reasonable.

Page J-12, section J.1.4. The distributions used in the assessment appear reasonable. The explanation of the distribution for fish consumption (page J-23) seems reasonable.

Page J-27, The exposure duration data appear reasonable.

Page J-28, Table J-15. These Minimum and Maximum values seem reasonable. The Maximum values appear somewhat large but ok for a high-end analysis.

Page J-31, Table J-16. The parameters in this table appear reasonable.

Page J-31, Table J-17. The values in this table appear reasonable.

Appendix K.

Page K-3, section K.2. The first paragraph is not clear.

Paragraph 2. The text says, "In this analysis, a regression analysis is applied to a linear equation to estimate…" This is not clear. What linear equation is the regression analysis applied to?

This is the first place that the document says that the sensitivity analysis is applied to the probabilistic simulation rather than the deterministic version of the model. Is there a difference between a sensitivity analysis on a probabilistic model and one on the deterministic version of the same model? I would not think so.

Paragraph 3, first sentence. This sentence raises a question. Is there a difference between a sensitivity analysis that identifies the most sensitive model parameter relative to small changes in input parameters vs. sensitivity to large changes in input parameters. The sentence implies that historically sensitivity analysis is focused on the latter. I thought it was focused on the former. Which is the case? This point highlights the fact that the introduction to this section does not give a good definition of sensitivity analysis.

Page K-4, equation K-1. The text on this page is not clear as to how this regression model is constructed. How many different points of the form (log y, x1,x2,…,xp) are used to determine the regression parameters in equation K-1? Do the values of the parameters in equation K-1 depend on the number of the points chosen? How do you know that they do not? How do you know that the points given a good representation of the model, that is, cover the range of possible outputs? None of this is discussed in your explanation.

Page K-5, paragraph 1. If you remove some of the variables from equation K-1 and try to fit the reduced equation to the same number of points of the form (logy, x1, x2,…,xp), will this cause a problem?

Page K-5, last paragraph, bullet 1. The text says, "The data set must contain only one record for each Monte Carlo iteration." Since 3,000 iterations were run in the Monte Carlo analysis, does this mean that 3,000 points were used to determine the parameters in Equation K-1? If this is so, it would make the explanation on page k-4 clearer if you said so.

Bullet 2. The method uses points of the form (logy, x1,x2,…,xp) to determine a response surface of the form given by equation k-1. Why does it matter that some of the input parameters are constant? Maybe one of the constant parameters is the most sensitive parameter in the risk model. Why isn't this information important?

Page K-6, bullet 2. Why does this matter? You want to find the risk model parameters that have the greatest impact of the risk estimate. Or are you trying to find the risk model parameters that for the same percentage change over their range have the greatest impact on the risk model output? Again, exactly what you mean by a sensitivity analysis has not been well defined in the introduction.

Specific Comments on Document No. 2 (The Risk Characterization)

Page 1, paragraph 3. I am in agreement that the current risk assessment represents an assessment of the risk to the "high-end" of the exposed population since it is for the farm family living on a farm (and obtaining a large percentage of their diet from their own farm products), where sewage sledge is land applied as a fertilizer or soil amendment. I am also in agreement that establishing numerical standards to protect this "high-end" exposed farm population from exposure to dioxins in sewage sledge will be protective of the general population.

Page 2, paragraph 4. The text says, "…the farmer never rotates the pasture to grow row crops where presumably, tilling of sewage sludge in the soil would occur to mitigate dioxin volatilization transport to the row crops." The point of this sentence is not clear. Is it that the rotation to grow row crops in pastureland would result in higher row crop concentrations because of higher application rates to pasture?

The exact percentages devoted to crop production and animals raising (pasture land) are unimportant as long as the farm produces sufficient crops and animal products to feed to farm family (using the consumption rates from the document).

Page 3, paragraph 2. There is no doubt that the scenario presented is a "high-end" exposure. Not only is the farm family assumed to live on the farm, but also it consumes a large fraction of its diet from farm grown food, an unlikely event. It may be that a farm family consumes a high fraction of some diet item (like fruit or vegetables) from farm-produced food, but it is very unlikely that any farm family obtains large fractions of all diet items (fruit, vegetables, meet, milk, chicken, eggs, fish, etc.) from their farm. Thus, this exposure scenario represents a “high-end” exposure.

Page 3, paragraph 5. The text says, “…high end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk.” It is not clear that a farm family living of a farm and obtaining a large fraction of their entire food intake from farm-produced food is a scenario that actually occurs. Thus, the risk computed as “high-end” in this assessment may be above that actually experienced by any real family living on a farm using sewage sludge. However, since the actual diet of a farm family living on such a farm is unknown, the exposure scenarios and assumption used in the present assessment are reasonable and appropriate.

Page 4, bullet 3. The text says, “Fractions of home produced beef, milk, eggs, and poultry …”. While these may be central tendency values, it is very unlikely that any farm family will actually consume farm-produced food as a major part of the entire diet. Thus, this assumption is a high-end assumption.

Page 4, bullet third from bottom. The text says, “Concentration of dioxin in aqueous phase of maternal milk- literature value.” From this assumption, it is not clear if the document is using background dioxin concentrations in maternal milk or calculated concentrations based on intake of dioxin in farm food. The first bullet on page 5 indicates the document is calculating the concentration of dioxin in maternal milk. Why then is a literature value for the concentration of dioxin in aqueous phase maternal milk used in this document?

Page 6, bullet 3. The text says, “It may also be acceptable to characterize this risk assessment as the “high-end” of the “high-end”. “ I agree with this statement. Because of the very conservative assumptions regarding dietary exposure (concurrent exposure to farm-produced meat, milk, fruit, vegetables and home-caught fish) for the farm family, I believe that this is a high-end of the high-end assessment.

Specific Comments on Document No. 3 (Estimate of Population Modeled and Annual Cancer Cases from the Modeled Population)

Page 1, bullet 2. The text says, “Two percent are the “high-end” modeled population that live on farms, raise their own crops and animals, and consume a significant portion of their annual diet from their farms,” I believe that this is an unrealistically high estimate. It may be that about two percent of the U.S. population lives on farms, but it is vary unlikely that they consume a significant portion of their annual diet from their farms. There are about 2 million farms in the United States and 1.56 percent of the U.S. population lived on farms in 1990 (U.S. census data). The percentage is undoubtedly less now. However, only about 100,000 of these farms are licensed to produce milk. Thus, the assumption that all of these farms produce milk for their own consumption is not realistic.

The probability that these same 100,000 farms also produce beef for home consumption is unlikely.

1997 U.S. farm census data show 1.9 million farms, 800,000 produce beef cattle, 116,000 produced milk, 106,00 have land in orchards and only 53,000 harvested vegetables. (**http://www.nass.usda.gov/census/census97/highlights/usasum/us.txt**)

Page 1, bullet 3. This is an over-estimate of the number of individuals in the high-end population.

Page 1, bullet 4. This assumption seems reasonable.

Page 1, bullet 6. What does the term “TSD” stand for?